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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,899	06/27/2003	Lisa M. Donnelly	022956-0218	7787

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EXAMINER	
BLANCO, JAVIER G	
ART UNIT	PAPER NUMBER
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,899	DONNELLY ET AL.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claim 1 in the reply filed on December 4, 2006 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 6, 7, 11-14, 16, 17, 20, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bolton (US 5,906,632 A).

Referring to Figures 1, 2, 3A, 4, and 6A-6F, Bolton discloses a graft fixation device comprising:

(i) A bioabsorbable (see column 4, lines 22-27) radially expandable sheath (anchor 20) having a bullet-shaped (see column 7, lines 1-4) slot-free distal tip (tip/point 222) with at least two sidewalls (212, 213) extending proximally therefrom and defining a central lumen (central lumen defined between bore 220 and bore 221), each sidewall having a substantially concave outer surface (grooves 210) capable of seating (see column 4, lines 8-15) a graft member (80, 82), and

each sidewall being at least partially separated by a longitudinally oriented opening (groove 218) extending from a proximal end (223) along a substantial length of each sidewall and terminating at a position just proximal to the distal tip (i.e., it does NOT open/terminate in distal tip 222, therefore it does not create a slot/slit therein); and

(ii) A bioabsorbable (see column 4, lines 42-44) sheath expander (screw 40) capable of being disposed in the central lumen of the radially expandable sheath, and CAPABLE OF flexing/deforming the concave outer surface of the sidewalls toward a circular geometry (see Figures 6A-6F; see column 4, lines 45-61). Alternatively, the "circular geometry" could be broadly interpreted as the circular geometry of the bone tunnel/bore (i.e., the concave outer surface of the sidewall will be deformed in the direction of the circular geometry of the bone tunnel/bore).

Bore 220 is capable of receiving guide wire/pin 36 (see column 3, lines 60-65). The sheath may comprise other alternate shapes (see column 6, lines 60-65). The invention may comprise a kit of expandable sheaths and expanders (see column 4, lines 16-21; column 6, lines 34-39), wherein a properly dimensioned (i.e., depends on the particular bone tunnel diameter and/or length) sheath/sleeve will receive a correspondingly dimensioned sheath/sleeve expander. Further, it is inherent that a range of sheath & expander pairs will be available to the surgeon in the operating room so as to accommodate variations in drilled hole/tunnel sizes.

4. Claims 1-7 and 11-17 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Justin et al. (US 6,887,271 B2).

Referring to Figures 1-6, Justin et al. disclose a graft fixation device comprising:

(i) A bioabsorbable (see column 6, lines 34-38) radially expandable sheath (fixation members 20, 50) having a bullet-shaped slot-free distal tip (tip/point 112) with at least two sidewalls (see Figures 2 and 6) extending proximally therefrom and defining a central lumen (eyelet 24 and/or opening 22, 55), each sidewall having a substantially concave outer surface (grooves 23) capable of seating (see column 4, lines 15-20; column 5, lines 3-8; column 7, lines 48-54) a graft member (200), and each sidewall being at least partially separated by a longitudinally oriented opening (slots 24, 360, 370) extending from a proximal end along a substantial length of each sidewall and terminating at a position just proximal to the distal tip; and

(ii) A bioabsorbable (see column 6, lines 34-38) sheath expander (expansion plug 21, 52, 310) capable of being disposed in the central lumen of the radially expandable sheath, and CAPABLE OF flexing/deforming the concave outer surface of the sidewalls toward a circular geometry (see column 4, lines 15-20; column 5, lines 3-8; column 7, lines 48-54). Alternatively, the "circular geometry" could be broadly interpreted as the circular geometry of the bone tunnel/bore (i.e., the concave outer surface of the sidewall will be deformed in the direction of the circular geometry of the bone tunnel/bore).

Openings 24, 22, 55 are capable of receiving guide wire/pin. The sidewalls include surface features 11, 12, with the proximal-most surface feature acting as a stop member. With regards to a kit comprising a plurality of expanders of varying sizes, it will be inherent that a range of sheath & expander pairs will be available to the surgeon in the operating room so as to accommodate variations in drilled hole/tunnel sizes. The invention may comprise a kit of expandable sheaths and expanders, wherein a properly dimensioned (i.e., depends on the

particular bone tunnel diameter and/or length) sheath/sleeve will receive a correspondingly dimensioned sheath/sleeve expander.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-4, 8, 9, 11-14, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. (WO 02/32345 A2; cited in Applicants' IDS).

Referring to Figures 1A, 2B, 3, 5A, 5B, and 6, Jacobs et al. discloses a graft fixation device comprising:

(i) A bioabsorbable (see page 3, lines 11-14; page 7, lines 9-24) radially expandable sheath (Figure 5A: device 190; Figure 6: saddle section 210 and rail portion 214) having a slot-free distal tip (Figure 3: distal tip) with at least two sidewalls (Figure 5A: spring arms 192, 194, 198, and 200) extending proximally therefrom and defining a central lumen (Figure 5A: central lumen and/or passageway 178), each sidewall having a substantially concave outer surface (exterior cavity 146, 196, 228) capable of seating a graft member, and each sidewall being at least partially separated by a longitudinally oriented opening (Figure 5A: longitudinally oriented openings between spring arms 192, 194, 198, and 200) extending from a proximal end along a substantial length of each sidewall and terminating at a position just proximal to the distal tip. The substantially concave outer surfaces include surface features (Figure 5A: barbs 204). The

sheath further includes stop members (Figure 5A: protuberances 202). Passageway 178 is capable of receiving a guidewire if one skilled in the art desires so.

(ii) With regards to the "bioabsorbable sheath expander", it is noted that the claim language does not recite structure defining said "bioabsorbable sheath expander", so the Examiner is broadly interpreting said "expander" as the tool (e.g., Figure 4D: pin 184), instrument, or wedge used to implant/manipulate the bioabsorbable radially expandable sheath. Said tool, instrument, screw, and/or wedge are well known in the art, and is capable of being disposed in the central lumen of the radially expandable sheath, and capable of flexing the sidewalls of the radially expandable sheath if one skilled in the art desires so. The "circular geometry" could be broadly interpreted as the circular geometry of the bone tunnel/bore (i.e., the concave outer surface of the sidewall is capable of being deformed/flexed in the direction of the circular geometry of the bone tunnel/bore). Also, the material of Jacobs et al.'s sheath/sleeve is the same as Applicants' sheath/sleeve, and intended for the same purpose (anchoring a ligament/tendon/graft). Expansion of the bioabsorbable radially expandable sheath (i.e., by introduction of an expander) will provide at the least some level of deformation of the concave surface towards a "circular geometry".

Jacobs et al. did not particularly disclose the material of the expander as a "biodegradable" material. However, this is well known in the art. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a biodegradable expander with the invention of Jacobs et al., since it has been held to be within the general skill of a worker in the art to select a know material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969)

7. Claims 5-7 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. (WO 02/32345 A2; cited in Applicants' IDS) in view of Hays et al. (US 2002/0072797 A1).

With regards to claims 5 and 15, Jacobs et al. disclose the invention as claimed in claims 1-4, 8, 11-14, 20, and 21, except for particularly disclosing a stop member at a proximal end of the sheath. However, this is already known in the art. For example, Hays et al. disclose stop members 1000 at a proximal end of sheath 400 in order to prevent over-insertion of the sheath into a bone tunnel (see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of adding stop members at a proximal end of an expandable sheath, as taught by Hays et al. (US 2002/0072797 A1), with the invention of Jacobs et al., in order to prevent over-insertion of said sheath into a bone tunnel.

With regards to claims 6, 7, 16, and 17, Jacobs et al. disclose the invention as claimed in claims 1-4, 8, 11-14, 20, and 21, except for particularly disclosing the expander as a tapered screw. However, this is already known in the art. For example, Hays et al. disclose sheath expanders

(such as tapered screw sheath expander 700) as insertable into central lumen 450 of expandable sheath 400 in order to deform or expand the sidewalls of said sheath. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of using a tapered screw as a sheath expander, as taught by Hays et al. (US 2002/0072797 A1), with the invention of Jacobs et al., in order to deform or expand the sidewalls of said sheath with said tapered screw.

Response to Arguments

8. With regards to the 103(a) rejection based on Jacobs et al. (WO 02/32345 A2; cited in Applicants' IDS), Applicants' arguments filed December 4, 2006 have been fully considered but they are not persuasive.

a. Regarding claim 1, the Applicants argue that Jacobs et al. does not disclose newly added (functional) limitation: "configured to deform the concave outer surface of the sidewalls toward a circular geometry". The Examiner respectfully disagrees. The "circular geometry" could be broadly interpreted as the circular geometry of the bone tunnel/bore (i.e., the concave outer surface of the sidewall is capable of being deformed/flexed in the direction of the circular geometry of the bone tunnel/bore). Also, the material of Jacobs et al.'s sheath/sleeve is the same as Applicants' sheath/sleeve, and intended for the same purpose (anchoring a ligament/tendon/graft). Expansion of the bioabsorbable radially expandable sheath (i.e., by introduction of an expander) will provide at the least some level of deformation of the concave surface towards a "circular geometry".

b. Regarding claim 11, it will be inherent that a range of sheath & expander pairs will be available to the surgeon in the operating room so as to accommodate variations in drilled hole/tunnel sizes. The invention may comprise a kit of expandable sheaths and expanders, wherein a properly dimensioned (i.e., depends on the particular bone tunnel diameter and/or length) sheath/sleeve will receive a correspondingly dimensioned sheath/sleeve expander.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

February 6, 2007

David H. Willse
Primary Examiner